

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF OKLAHOMA

IN RE: GENENTECH HERCEPTIN)
(TRASTUZUMAB) MARKETING AND SALES) No. 16-MD-2700-TCK-TLW
PRACTICES LITIGATION.)

TRANSCRIPT OF MOTION HEARING
BEFORE THE HONORABLE T. LANE WILSON
UNITED STATES MAGISTRATE JUDGE
AUGUST 3, 2016

REPORTED BY: BRIAN P. NEIL, RMR-CRR
United States Court Reporter

*Brian P. Neil, RMR-CRR
U.S. District Court - NDOK*

1 you got to hit to the one-thousandth to be within that
2 warranty.

3 And so isn't the question then whether or not, in light
4 of each state's warranty law, you're essentially close enough
5 to meet that warranty?

6 MR. O'CONNOR: Well, the reason that Judge Kern
7 concurred with us that federal preemption was a threshold issue
8 and that discovery was stayed on the merits and on class
9 certification was forecast in our filing of June 20, a 10-page
10 preview of what our summary judgment would be.

11 And in that, and in the course of discovery, we've
12 shown them the specification for this product. And Your Honor
13 is exactly right, we don't have to pinpoint this. The
14 FDA-approved specification as in our papers reveals that it's
15 440 mL, xxxx xx xxxxx xx. So that's the range. And because
16 there's a range on content, there's necessarily a range on the
17 numbers you're referring to on the concentration.

18 So here we are -- here we are dealing with efforts to
19 get all kinds of discovery. And, Your Honor, we've brought
20 with us what we produced. It's the product of, you know, 20
21 people searching in four different product groups. It's been a
22 massive review and production effort in a short time frame.

23 But all that is to say, that's the whole issue on the
24 preemption, that the -- the state warranty laws would be
25 preempted because the federal law does not require that each

1 vial of Herceptin contains 440 mL. So --

2 THE COURT: Right. So if that's the case, and your
3 position is that federal law allows you some reasonable
4 variation, why is it for -- and that's your preemption defense,
5 or at least one of them -- why is it the plaintiffs don't get
6 to go behind that and try to figure out, you know, what it is
7 Genentech considers to be a reasonable variation and what it
8 can or did or didn't do with respect to the formulation and the
9 label changes in its product?

10 MR. O'CONNOR: Well, one is, we did go behind it.
11 we produced every certificate of analysis on every lot that's
12 ever been distributed in the United States or since 2010, the
13 date that they've imposed here, and every one of those pages
14 which gives great detail about everything. But it also says,
15 here's the content of the Herceptin. So there's some that say,
16 you know, [REDACTED], some say [REDACTED], some say [REDACTED], whatever it is for
17 every --

18 THE COURT: Right. But why is it that they don't
19 get to see -- I mean, why is it not discoverable? And maybe I
20 misunderstand what you have produced. But my understanding is
21 that you have not produced any, for example, internal e-mails
22 or documentation that would indicate how you got to those
23 numbers or how you -- how you determined what the labeling
24 would be in light of those numbers or communications you had
25 with the FDA about those numbers. I mean, why -- why do they

1 So, Mr. Keglovits, what -- tell me what you're looking
2 for in that.

3 MR. KEGLOVITS: Well, to the extent that there was
4 approval by the FDA for finished product release testing, we
5 want them to tell us what those range of results were. Again,
6 they said you can find it in the CMC just as easily as we can.
7 We don't want to have to try to guess, we just want them to
8 tell us.

9 MR. O'CONNOR: Your Honor.

10 THE COURT: Go ahead.

11 MR. O'CONNOR: We produced 221 certificates of
12 analysis that reflect exactly this. There's an example of a
13 certificate of analysis that says exactly what came out of each
14 lot. So we have -- we have a --

15 (Discussion held off the record)

16 MR. O'CONNOR: It shows the exact -- here's one of
17 August 10 of 2012, and the concentration on the content here
18 was [REDACTED] per vial, and that goes -- it goes into much more
19 than that on each one of these.

20 So now, I guess, is the suggestion that we need to go
21 assimilate and write down every -- what every one of these
22 certificates establishes.

23 THE COURT: I think what you could do -- I'm looking
24 at your answer and I'm -- I don't -- I think what you could do
25 is refer the plaintiff to the specific Bates numbers that

MR. ADAMS: [1] 3/8 MR. EGLI: [6] 3/16 31/23 31/25 55/14 81/7 81/9 MR. KEGLOVITS: [48] 3/6 3/22 4/5 13/20 13/25 14/4 21/3 42/18 42/21 42/24 43/17 44/6 44/16 45/5 45/10 45/12 45/18 46/1 46/4 46/9 48/4 48/16 49/1 50/1 52/2 53/18 54/2 55/21 55/25 56/4 56/16 56/20 57/2 59/20 62/22 63/3 64/14 64/22 64/24 65/2 65/5 67/6 73/23 74/23 77/18 78/25 80/3 80/19 MR. O'CONNOR: [46] 3/13 3/24 5/4 6/5 7/9 8/2 10/7 10/13 12/14 12/23 37/12 37/20 37/23 42/15 42/20 43/7 43/12 43/21 44/19 46/13 46/15 46/18 47/1 47/13 47/19 47/22 50/6 51/4 52/8 52/10 52/15 53/3 53/11 69/18 77/21 77/23 78/4 78/10 78/15 78/20 79/5 79/15 79/18 79/21 79/24 80/2 MR. PEBSWORTH: [5] 3/9 67/9 68/14 69/11 69/15 MR. SILL: [1] 3/11 MS. DONAHUE: [68] 3/15 22/4 22/6 22/10 25/17 25/22 26/15 26/22 27/10 27/16 28/2 28/9 28/11 28/21 28/23 29/5 29/24 30/4 30/14 30/20 30/25 31/3 31/5 31/24 32/2 32/13 32/17 33/6 33/11 33/14 34/7 35/5 36/14 36/19 36/25 37/8 39/23 40/7 40/18 55/7 55/12 56/10 57/13 57/17 57/25 59/2 61/14 62/14 62/19 63/4 64/7 64/12 66/5 70/25 71/6 75/14 76/1 76/6 77/7 79/25 80/6 80/9 80/13 80/15 80/17 80/21 80/25 81/6	MS. FOGLEMAN: [1] 3/10 THE COURT: [153] '97 [1] 40/20 'earnestly [1] 17/7 'specifically [1] 17/8 1 10 [3] 5/14 41/17 52/17 10-page [1] 6/9 100 [1] 2/4 10:30 [1] 64/6 11 [1] 41/21 1100 [1] 2/4 1192 [1] 16/24 1197 [1] 17/13 1198 [1] 18/3 12 [7] 5/15 43/19 43/20 46/9 46/13 46/15 51/24 12 but [1] 46/17 14 [1] 62/4 140 [3] 32/2 32/3 32/3 14005 [1] 2/6 15 [2] 2/10 33/8 15-day [1] 33/16 15-page [1] 66/18 16 [1] 62/5 16-MD-2700-TCK-TLW [1] 1/5 17 [1] 5/10 18 [2] 53/13 64/25 1996 [1] 21/14 1997 [2] 12/19 57/23 1998 [4] 24/4 38/14 41/9 54/3 2 2,000-page [1] 76/9 20 [2] 6/9 6/20 20 percent [1] 58/11 20.2 [1] 5/17 20.952 [3] 5/19 5/19 5/21 2000 [3] 19/25 23/24 54/4 2002 [1] 21/10 2008 [1] 23/24 2010 [4] 7/12 23/24 40/13 41/8 2012 [1] 52/17 2013 [1] 23/24 2015 [1] 56/4 2016 [3] 1/16 3/1 82/15	21 [5] 19/3 21/16 51/13 53/14 53/21 21 mg [2] 38/6 50/11 21 mL [1] 53/22 21.8 [2] 21/16 51/1 22 [2] 10/19 10/22 221 [1] 52/11 2555 [1] 2/13 26 [1] 51/8 2700 [2] 2/10 2/15 28th [1] 78/12 29 [2] 10/23 78/8 3 3.6 percent [2] 4/22 5/18 30 [5] 11/16 66/24 66/24 66/24 67/22 301 [1] 19/4 3:00 Wednesday [1] 64/12 4 4,000 [1] 47/8 4,000-page [2] 42/20 48/12 400 [3] 4/13 4/17 5/2 5 5th [1] 2/4 6 61 [1] 4/4 64 [4] 4/4 4/10 78/12 78/24 64108 [1] 2/13 65 [1] 4/4 6th [2] 2/10 82/15 7 73013 [1] 2/7 74103 [1] 2/4 74119 [1] 2/11	8 86 [1] 78/7 9 94104 [1] 2/15 9th [1] 35/20 A ability [3] 4/24 69/4 74/3 able [15] 15/2 30/22 33/21 40/4 40/25 41/9 44/4 49/16 50/9 54/7 54/8 58/14 59/25 68/23 75/19 about [108] above [3] 26/6 27/1 82/8 above-captioned [1] 82/8 absence [1] 50/10 absent [1] 18/5 absolutely [2] 59/14 75/25 accepting [1] 26/21 access [1] 72/15 accomplish [1] 60/14 accomplished [1] 60/1 accumulate [1] 14/3 accurate [1] 82/6 acquired [1] 17/17 across [1] 70/21 Act [1] 19/3 acting [2] 21/1 38/25 action [1] 82/11 actions [1] 71/12 actual [3] 17/14 45/16 57/4 actually [11] 10/6 14/22 15/24 19/9 19/14 22/15 54/23 55/2 57/16 61/6 71/21 Adam [1] 2/3 Adams [2] 2/3 3/9 add [1] 47/18 adding [1] 50/23 addition [2] 50/21 78/21 additional [4] 8/20 23/23 27/18 33/4 address [4] 4/4 39/17 70/3 77/15 addressed [1] 64/24 addresses [1] 65/24 administration [1] 17/18 admitting [1] 32/25 adopted [1] 56/3
			(1) MR. ADAMS: - adopted